THE UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

United States of America, Plaintiff, *ex rel.* Leanne Houston, Relator, v. Medtronic, Inc., Defendant.	Civ. No. 2:20-cv-3367-BHH **RESPONSE TO MOTION TO DISMISS**

Relator Leanne Houston, by and through her undersigned counsel, hereby responds in opposition to Defendant Medtronic, Inc.'s motion to dismiss the Amended Complaint, which alleges substantive and retaliation claims under the False Claims Act (FCA).

At the end of April 2018, Relator Leanne Houston was Medtronic's top sales representative in the entire country. In the preceding twelve months, Ms. Houston's biggest responsibility had been the "conversion" of McLeod Health Inc. (McLeod), a hospital network in northeastern South Carolina. A "conversion" was a sales campaign to persuade a hospital network to contract to use only Medtronic's surgical products and to terminate its relationships with competing suppliers. Medtronic "converts" hospital networks to use its products exclusively by aggressive marketing campaigns aimed at non-physician decisionmakers at the hospital. To persuade these decisionmakers, Medtronic promises to undercut competitor prices significantly, which requires cutting costs somewhere, which is why Medtronic's surgical staplers, among other devices, are of notoriously poor quality and comprise 95% of all staplers recalled from the market.

The poor quality of Medtronic's surgical staplers is well known and has been the subject of many lawsuits and regulatory actions. What was not well known and what Ms. Houston relates as an original source, based on insider information, is that in late August 2018, she began reporting concerns raised by McLeod surgeons that Medtronic's GIA80 surgical staplers were defective and were causing serious harm to patients. Medtronic responded by concealing the defect to avoid a recall, which it did by falsely reporting the adverse incidents to the U.S. Food and Drug Administration (FDA) and by telling non-surgeon executives at McLeod that the issue was user error, when it knew that was not the case. Ms. Houston was not willing to conceal the defect to help preserve the "conversion," so in October 2018 she was suspended and in early December 2018 she was informed she would be terminated for "incompetence." Her job performance, however, was so excellent that on the day she was terminated she was still the top sales representative in her region—even with the extra three months of her suspension, no one could catch up with her.

Medtronic's fraudulent concealment of the defect in its GIA80 staplers caused serious injury to many patients at McLeod, and, doubtlessly, other hospital networks. It also caused the Government to pay for surgical procedures made worthless by the defective surgical staplers, because those procedures caused further injury to patients. Medtronic's retaliation against Ms. Houston for her whistleblowing to protect patients unable to protect themselves as they lie unconscious in an operating room left her as an unemployed single parent in her 50s with no ability to obtain employment in the industry she had worked in for thirty years.

I. Background

A. Factual Background

1. Relator was Medtronic's top sales representative.

Relator Leanne Houston finished graduate school in 1989, with a master's degree in business administration earned after her bachelor's degree in marketing. Am. Compl. ¶ 46. She began working in medical sales in 1990 for Procter & Gamble. Am. Compl ¶ 47. She held various sales roles with Boston Scientific and Covidien and was hired as a sales executive at Covidien in December 2013, shortly before Medtronic acquired it. *Id.* Ms. Houston finished in the top 20% of her Medtronic trainee class and won a national sales contest in her first two years. Am. Compl. ¶ 48. She was promoted to combined sales executive in 2015. *Id.* Her sales territory included eastern South Carolina. Am. Compl. ¶ 49.

In November 2017, she became responsible for the "conversion" of McLeod. *Id.* As noted above, "conversion" was a Medtronic sales campaign to persuade a hospital network to contract to use only Medtronic's surgical products and to terminate its relationships with competing suppliers. *Id.* The McLeod conversion led by Ms. Houston succeeded, Am. Compl. ¶ 50, and on April 26, 2018 (the end of Medtronic's fiscal year), Ms. Houston was the number one Minimally Invasive Therapies Group sales representatives in the entire country, measured by performance against sales quota, Am. Compl. ¶ 53. In her fiscal year 2018 performance review, written in June 2018, Ms. Houston received an "Excellent" rating and exceeded all sales goals. Am. Compl. ¶ 54. Her performance evaluation praised her "record year!" and "successful full line conversion at 6 McLeod hospitals," noting a "successful management of full transition of all hospitals to rely solely on Leanne for all issues and questions," "successfully addressed and handled surgeon resistance to change, training and adoption of new technology, price issues, coordination of manpower, communication to multiple hospitals, etc., as well as significant rolling back orders and

supply challenges . . . . Strong work Leanne." Am. Compl. ¶ 54. Ms. Houston's June 2018 performance review also praised her for as someone who "Models Ethical Behavior," "Demonstrates courage," and "holds team accountable for ethical behavior." Am. Compl. ¶ 58. That praise is ironic given Medtronic's retaliation, only a few months later, for her courageous attempt to hold it accountable for ethical behavior.

On July 7, 2018, Ms. Houston was promoted again and given a substantial raise. Am. Compl. ¶ 56.

2. Relator reported dangerous defects with Medtronic's surgical staplers.

After the conversion led by Ms. Houston, McLeod surgeons used Medtronic surgical staplers without issue from February 2018 to August 2018 without issue. Am. Compl. ¶ 52. In mid-August 2018, however, McLeod surgeons began persistently and vociferously complaining about adverse incidents with GIA80 surgical staplers causing patient injury. Am. Compl. ¶ 60. The GIA80 stapler is a surgical stapler used to connect internal tissues in gastrointestinal procedures like organ resections. Am. Compl. ¶ 61. It is a simple stapler functionally identical to the Ethicon stapler McLeod surgeons had used before the "conversion" to Medtronic. *Id.* It lays staggered rows of staples and simultaneously cuts and divides tissue between the two rows with a steel blade. *Id.* The surgeons were complaining that the staplers were causing bleeding because they were cutting past the staple line due to a manufacturing defect. Am. Compl. ¶ 62.

The defect occurred in one or more lots of GIA80 staplers due to Medtronic's willful failure to conform to "current good manufacturing practice" (cGMP) as required by FDA regulations. Am. Compl. ¶ 63. *See also* 21 U.S.C. § 360j(f); 21 C.F.R. §§ 820 *et seq.* Medtronic has a long history of failure to conform to cGMP in manufacturing its surgical staplers, resulting in various defects necessitating recalls. Am. Compl ¶ 64. Of all surgical stapler and surgical staples recalled from 2013–2019, Medtronic had 3,284,551 devices recalled, while its closest competitor recalled

only 156,780 devices. *Id.* Medtronic devices accounted for over 95% of the total volume of surgical stapler and surgical staples recalled. *Id.* In fact, Medtronic's defective staplers are a principal reason the FDA terminated the Alternative Summary Reporting Program in 2019 and why the FDA, on October 8, 2021, reclassified tissue staplers for internal use from Class I medical devices to Class II medical devices subject to premarket notification and mandatory special controls. Am. Compl. ¶¶ 65–66.

At McLeod in late 2018, Ms. Houston was the surgeons' point-of-contact with Medtronic. Am. Compl. ¶ 67. Seven separate McLeod doctors informed Ms. Houston of at least ten staple line bleeds between August 18, 2018, and October 3, 2018, with the GIA80 stapler. *Id.* Ms. Houston reported each to her managers at Medtronic and completed the required internal company paperwork. *Id.* These injuries resulted in additional surgeries, blood transfusions, extended stays in the ICU, sepsis, possible death, and other complications. *Id.*

Date	**Surgeon**	**Procedure**	**Comment from surgeon:**
08/18/2018	Dr. Sonfield		
08/19/2018	Dr. Murrell	Appendectomy	"staple line bled X 5"
08/28/2018	Dr. Brewton		
08/29/2018	Dr. Richey	Gastro jejunostomy	"bleeding from anastomosis requiring transfusion and possible take back to operating room pending." noted patient injury. transfusion needed after patient left OR.
09/01/2018	Dr. Murrell	Gunshot patient	Voicemail to Ms. Houston at 2:00am
09/02/2018	Dr. White	Gunshot patient Lower Anterior Resection	mentions to Houston he's been having multiple issues, that "this isn't like us", meaning Medtronic.
09/14/2018	Dr. Sonfield	Ruptured diverticulitis	Showed a video of staple line bleeding to Ms. Houston
09/17/2018	Dr. Player	Appendectomy	"Pulsating arterial bleeding @ staple line." "Not isolated. Frequently with all my

Date	Surgeon	Procedure	Comment from surgeon:
			partners." "Return to Ethicon staplers."
09/17/2018	Dr. Sonfield	Appendectomy	"Says it is at the end. Like the knife is cutting past the staple line." Showed Ms. Houston video of staple line bleeding during surgery.
09/18/2018	Dr. Brewton	Resection of small bowel	"Staple line was torn from small bowel and bleeding. Had to resect small bowel three times and over sew staple line with silk. Unacceptable."
09/18/2018	Dr. White	"A colon case"	Gave Ms. Houston a video of the bleeding on Sept. 25
10/03/2018	Dr. Selander		GIA80 retrieved and sent to QA

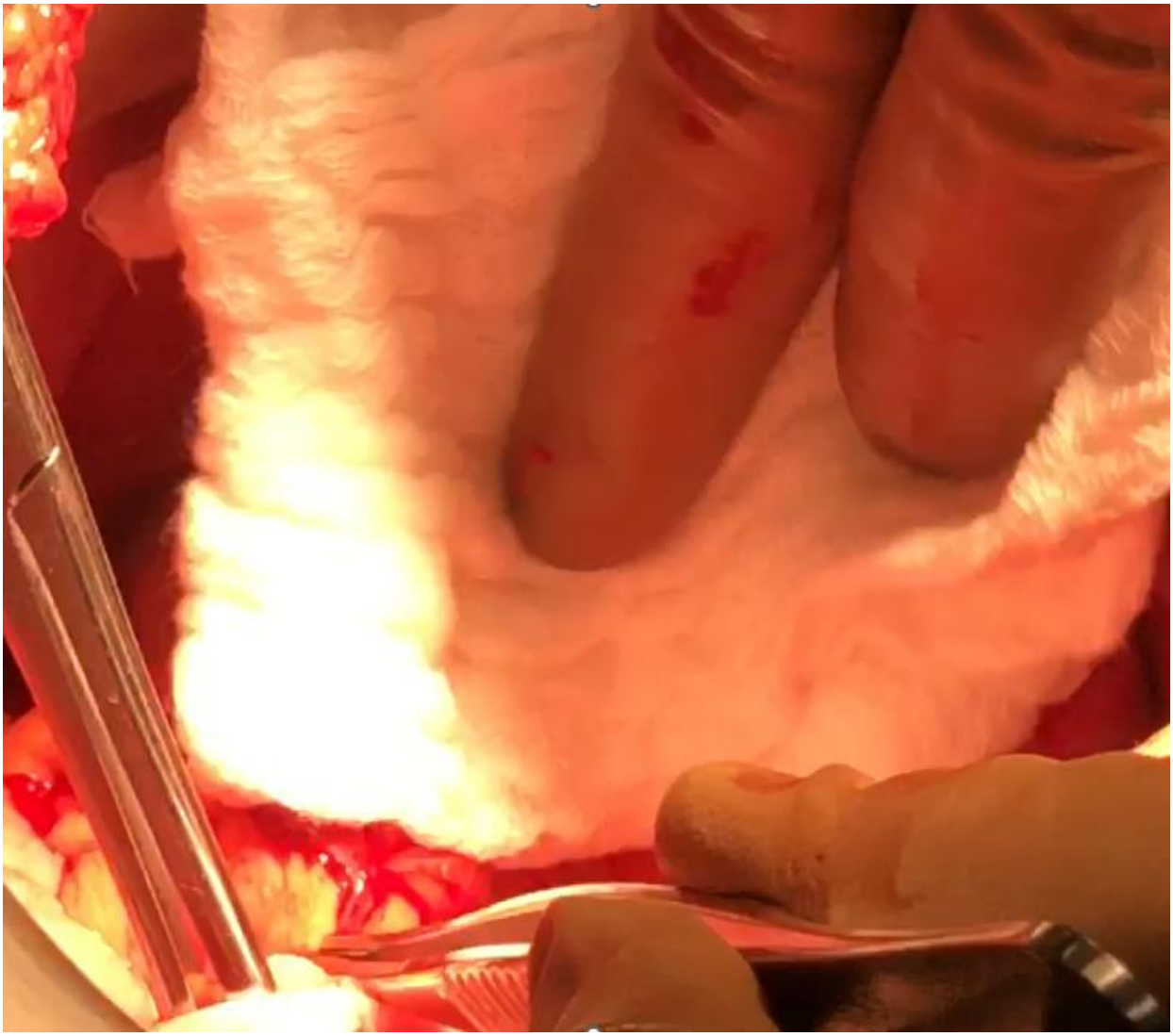
McLeod surgeons submitted numerous product complaint forms to Medtronic through Ms. Houston in August and September 2018. Am. Compl. ¶ 68. For example, on August 31, 2018, a surgeon submitted a form stating the GIA80 "fail to work on many occasions. These should not be used period." *Id.* A day later, Dr. Murrell submitted a form stating, "Entire staple line bled + S -> I had to oversew all", "On gastric resection, stapler fired halfway and then would not advance or retract", "THESE STAPLERS ARE DANGEROUS", and "These staplers are dangerous to pt care. I have never seen staple line bleeding like this in 20 years." *Id.*

On August 30, Ms. Houston notified her Medtronic sales manager, Barrett Garner, that she had received a second complaint in two days on the GIA80 stapler. Am. Compl. ¶ 69. As the complaints rolled in, Ms. Houston kept Mr. Garner up to date. *Id.* When Mr. Garner failed to take action, Ms. Houston communicated with Mr. Garner and his boss, Medtronic Area Vice President of Sales Chuck Bland, and other Medtronic personnel. *Id.* Over fifty people were aware of the bleeds. *Id.* More than 31 text messages, videos of patients bleeding during surgery, voicemails from customers, hospital complaint forms for each incident, and emails, were sent. Ms. Houston

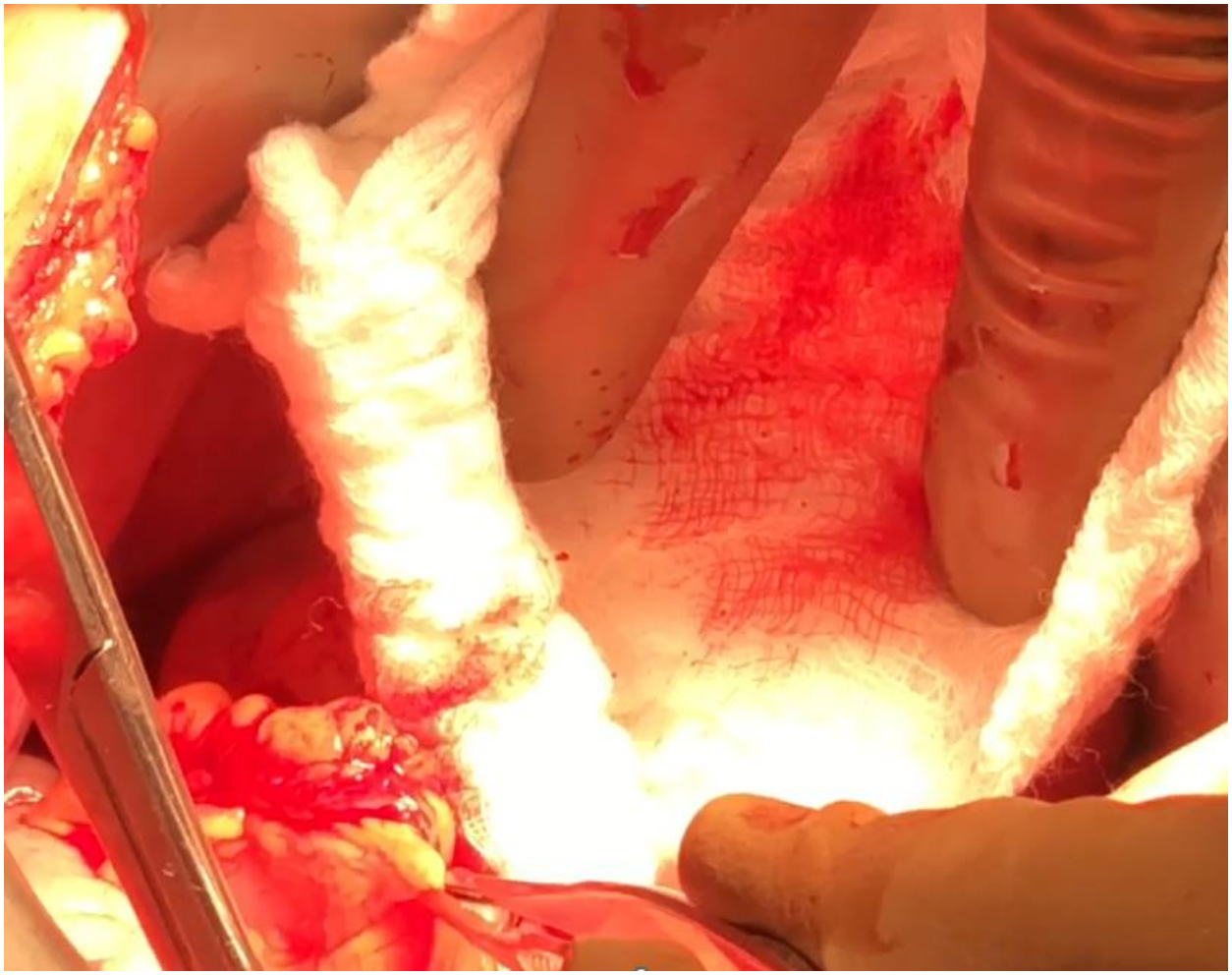
asked Mr. Garner if they could remove a GIA stapler from the shelf and have it tested. Am. Compl. ¶ 70. His response was a harsh "no", that would be "instigating a recall at her level." *Id.* Ms. Houston then asked if he wanted her "to stand there and watch the patient bleed?" *Id.* Mr. Garner replied "yes, and then send the product in to be tested." *Id.*

On September 18, 2018, Angela Putnam, McLeod's "Value Analysis Coordinator," sent an email to Ms. Houston and Mr. Garner, stating, "The attached items have presented with numerous complaints, from various surgeons, in which you have been notified and asked to investigate. Given the severity of these concerns, what are our next steps and best options to ensure safe patient care?" Am. Compl. ¶ 71. The next day, on September 19, 2018, a transcribed meeting was held about concerns with Medtronic products, including the GIA80. Am. Compl. ¶ 72. It was led by Dr. Michael Rose (a Vice President at McLeod who was considered the "champion" and leader of the conversion on the McLeod side—a physician but an anesthesiologist serving as a full-time hospital executive, not a surgeon). *Id.* Ms. Houston and Mr. Garner attended. *Id.* At the transcribed meeting, a nurse reported, "the surgeons feel like we are compromising quality of care that we are providing to these patients. Now they are seeing bleeding around the staple lines with the previous product they were not. . . . The surgeons are having to sew over the staple line." *Id.* Mr. Garner promised an action plan. *Id.*

Thereafter, on September 25, 2018, Dr. White, a surgeon considered an ally of the Medtronic "conversion," provided Ms. Houston a copy of a video of a bleeding event that occurred in a colon procedure a week earlier to demand that Medtronic to do something about the defective stablers. Am. Compl. ¶ 73. Below are two still frame images from the video.



The above image shows the surgeon placing a clean white gauze next to the staple line in the patient's colon, within the open abdominal cavity. The below image shows the same gauze covered in blood less than ten seconds later. The gauze did not touch the staple line in the colon; as can be seen in the video, the blood squirted from the colon with each heartbeat and sprayed the gauze and the surgeon's fingers. This is a serious and injurious surgical complication requiring immediate corrective action. A patient in a different procedure less than three weeks before this required a blood transfusion because of such bleeding.



On September 27, 2018, another meeting was held with Dr. Rose. Am. Compl. ¶ 74. Mr. Garner, Mr. Bland, and Ms. Houston attended. *Id.* Dr. Rose said he had been "a tad bit anxious about things lately." *Id.* Mr. Bland suggested switching McLeod surgeons to a different stapler. *Id.* Ms. Houston, however, would not adopt the party line of "user error," given that the surgeons had used the staplers without issue for months, and she would not discount the obvious possibility of a defective lot of staplers. *Id.* On October 1, 2018, another hospital C-suite meeting with Dr. Rose was held to discuss complaints about the staplers. Am. Compl. ¶ 75. Mr. Bland attended with Ms. Houston. *Id.* McLeod asked to switch back to the competitor Johnson & Johnson stapler they had used before switching to Medtronic's GIA80. *Id.* Mr. Bland countered by offering instead to switch from the GIA80 to a different, more expensive Medtronic stapler that would be

offered at the same price. *Id.* Mr. Bland told Dr. Rose to keep in the planned conversion of other divisions at McLeod and to "think of the rebates and savings to come. We need to get this situation under control." *Id.* Ms. Houston again would not adopt the party line of "user error," given that the surgeons had used the staplers without issue for months, and she would not discount the obvious possibility of a defective lot of staplers. *Id.*

On October 7, 2018, Mr. Bland yelled at Ms. Houston in front of other Medtronic employees, stating that he didn't ever want to hear her discuss the possibility of a lot number issue with the GIA80 stapler again, that she was putting the "conversion" at risk. Am. Compl. ¶ 76. On October 9, 2018, Mr. Garner provided the promised action plan—instruct surgeons to switch from the GIA80 to other staplers made by Medtronic, particularly the more expensive "TriStaple" stapler used in thoracic procedures. Am. Compl. ¶ 77.

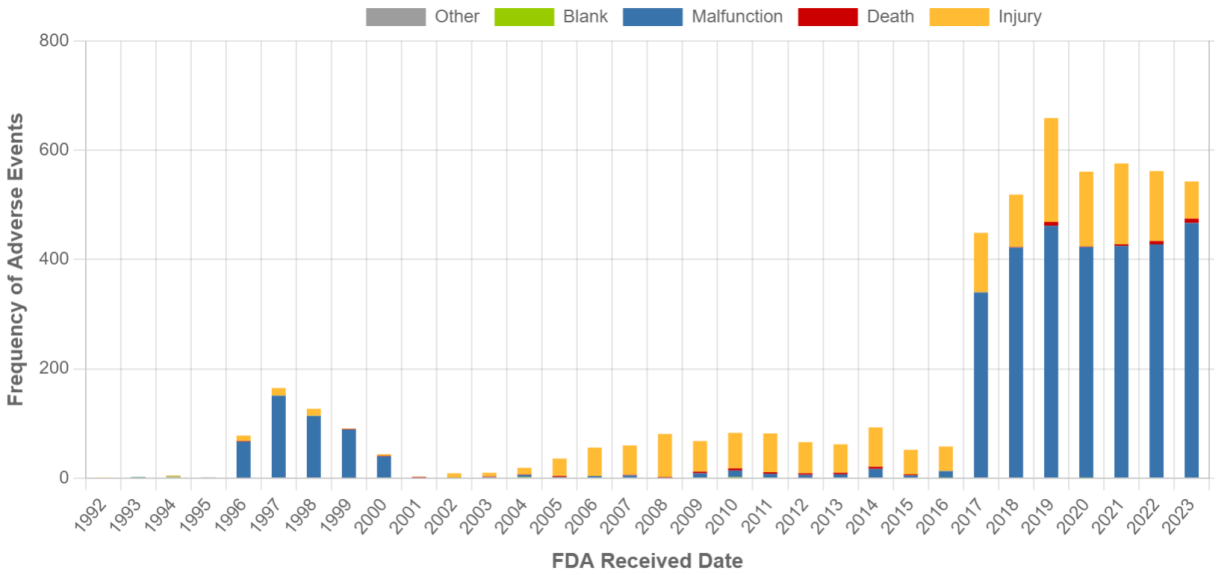
The defect in the GIA80 staplers at McLeod was caused by Medtronic's willful failure to conform with cGMP as required by law. Am. Compl. ¶ 78. Some of the victims of the above-reported procedures using Medtronic's defective staplers were Medicare (e.g., the ruptured diverticulitis case) or Medicaid (e.g., the gunshot case) beneficiaries. *Id.* All Medtronic staplers in the period August 19 to October 3 were defective, including those used in procedures billed to Government beneficiaries in that period. *Id.* This is precisely why Mr. Garner told McLeod to cease using the GIA80 and to instead use different models of surgical staplers. *Id.* He knew the GIA80 was defective. *Id.*

3. Medtronic fraudulently concealed the dangerous defects and continued to injure patients.

Medtronic was required to submit Medical Device Reporting reports (MDRs) to the FDA on adverse incidents resulting in patient injury within five business days. Am. Compl. ¶ 80. But Medtronic intentionally misreported adverse events with its stapler products at McLeod hospitals

from 2017–2019, Am. Compl. ¶ 81, which was part of its long standing practice of concealing multiple stapler defects. In 2001, Medtronic applied for exemption from the typical MDR reporting program under the Alternative Summary Reporting (ASR) Program. Am. Compl. ¶ 82. The ASR program was in place until 2019 and was intended to provide a simpler way for manufacturers to report well known malfunctions that did not affect the patient. *Id.* The FDA ended this program in 2019 after news reports disclosed that the adverse events reporting surgical stapler device failures causing patient harm submitted to the ASR program had hidden the data, preventing physicians from learning the true failure rates of surgical staplers. *Id.* Medtronic, in particular, often illicitly hid adverse incidents resulting in patient injury or risk of patient injury in ASRs. Am. Compl. ¶ 83. It also hid them by reporting products under obscure subsidiary company names like "US Surgical Puerto Rico." *Id.*

Medtronic, however, ceased reporting stapler-related reports through the ASR program after July 2017. Am. Compl. ¶ 84. The resulting spike in MDR adverse incident reports for Medtronic GIA staplers is obvious:



At the time Ms. Houston was reporting new defects with certain staplers at McLeod, Medtronic had just lost its primary means of concealing defects to avoid costly recalls. Am. Compl. ¶ 82–85. And, as noted above, 95% of all surgical stapler and surgical staples recalled from 2013–2019 were Medtronic products. Am. Compl. ¶ 86. In its first 2018 stapler recall, Medtronic revealed that "five people were injured related to missing components that could affect staple alignment" involving the "Endo Gia Articulating Reloads with Tri Staple Technology." Am. Compl. ¶ 87. This recall involved 171,271 units and drew significant media attention. *Id.* Medtronic later recalled 3,113,280 units of the Endo GIA Stapler in the Spring of 2019 for failure to fully insert staples. *Id.*

Only three months after Medtronic's first 2018 recall caused by five reported injuries (Medtronic recall May 2018 FA868), Ms. Houston was reporting at least ten staple line bleeds—twice as many injuries—at McLeod Hospital. Am. Compl. ¶ 88. These injuries involved a different stapler that was not included in the over 3 million devices recalled in 2018 and 2019 by Medtronic. *Id.* The injuries at McLeod were caused by a manufacturing problem which should have led to a recall. Am. Compl. ¶ 89. The problem was not caused by user error, as the McLeod surgeons had been successfully using the device for months before the rash of complaints beginning shortly the six-month business review on August 16, 2018 (at which there were no complaints regarding the GIA80 stapler). *Id.*

Medtronic wanted to avoid yet another stapler recall, and it did so in part by incorrectly reporting the McLeod adverse incidents to the FDA. Am. Compl. ¶ 90. For example, the MDR for Dr. Sonfield's issue during a procedure for perforated diverticulitis states:

US SURGICAL PUERTO RICO GIA; STAPLE, IMPLANTABLE Back to Search Results

Model Number GIA8038S
Device Problem Failure to Form Staple (2579)
Patient Problem No Code Available (3191)
Event Date 09/15/2018
Event Type Injury
Manufacturer Narrative
(b)(4) (ovewsew) if information is provided in the future, a supplemental report will be issued.

Event Description
According to the reporter, when stapling small bowel during a laparoscopic colon perforated diverticulitis small bowel, there was an incomplete staple line.The surgeon said that the stapler cut beyond the staples and was bleeding.It was stated that the bleeding was on the third reload or firing.They had to oversew to fix the bleeding staple line.

Brand Name	GIA
Type of Device	STAPLE, IMPLANTABLE
Manufacturer *(Section D)*	US SURGICAL PUERTO RICO 201 Sabanetas Industrial Park Ponce PR 00716 4401
Manufacturer *(Section G)*	US SURGICAL PUERTO RICO 201 Sabanetas Industrial Park Ponce PR 00716 4401
Manufacturer Contact	Lisa Hernandez 60 Middletown Ave. North Haven, CT 06473 2034925563

The narrative reflects what Dr. Sonfield reported, that the stapler cuts beyond the staple line. *Id.* But Medtronic reported it incorrectly. It reported the problem coded as "Failure to form staple (2579)" which the FDA defines as "Problem associated with the device failing to connect tissue with a stapling device due to the staples not forming correctly"—a problem with the staples rather than the stapler. *Id.*

Medtronic also avoided a recall by demanding Ms. Houston stop raising the issue. Am. Compl. ¶ 91. Ms. Houston brought complaints about the GIA to Mr. Garner's supervisor, Area Vice President of Sales Chuck Bland, and to the Medical Director of the Company, to the Global Quality Director, to the Stapling Product Manager, to Human Resources and to the Legal Department of Medtronic, among others. Am. Compl. ¶ 92. She did so because the stapler's unreliability put patient safety at risk. *Id.* In response, Mr. Bland angrily yelled at her on October

7, 2018, in front of other Medtronic employees, stating that he didn't ever want to hear her discuss the possibility of a lot number issue with the GIA80 stapler again, that she was putting the "conversion" at risk, meaning Medtronic's sales campaign intended to cause McLeod to cease to use competitor products and to use Medtronic staplers exclusively. Am. Compl. ¶ 93. Medtronic "converts" hospital networks to use its inferior products exclusively by aggressive "conversion" marketing campaigns aimed at non-physician decisionmakers at the hospital. Am. Compl. ¶ 94. To persuade those decisionmakers, Medtronic promises to undercut competitor prices significantly. *Id.* Doing so despite the expensive marketing campaign requires cutting costs somewhere, which is why Medtronic does not follow cGMP in manufacturing products like staplers, which explains why Medtronic staplers comprise 95% of all stapler recalls and why Medtronic resorts to fraudulent practices to avoid even more stapler recalls. *Id.*

4. Medtronic retaliates against Ms. Houston.

All Ms. Houston's concerns about the GIA80 stapler were made prior to Medtronic taking adverse action against Ms. Houston as an employee, and in fact were the impetus for Medtronic's retaliatory actions against Ms. Houston. Am. Compl. ¶ 95. Ms. Houston was a star sales representative until the very last months of her employment. Her sales numbers were among the best in the country. Am. Compl. ¶ 96. She had recently secured a $2.2 million dollar account that opened the door to even more expansion in her eastern South Carolina territory. *Id.* She had just been awarded "President's Club," a promotion, a substantial raise, and had a spotless review from her supervisor. *Id.* Her customers loved and trusted her. *Id.* Her peers respected her. *Id.* She had every intention to spend the rest of her career at Medtronic, a company she had loved and long admired. *Id.*

But in her last months of employment, Ms. Houston raised a product safety concern regarding a bad batch of surgical staplers. Am. Compl. ¶ 98. Her supervisors responded by

inventing a litany of false performance critiques and outright lies attempting to tie her to the staple line bleeds and summarily fired her. *Id.*

On October 17, 2018—only ten days after Mr. Bland told her never to discuss any possibility of a defect with the GIA80 staplers—Mr. Garner and Mr. Bland told her she was not working hard enough and told her that she was required to "sign in" by 7am every day—no other sales representatives were required to do that. Am. Compl. ¶ 99. On October 19, 2018, Mr. Garner sent a letter to Mr. Bland and to human resources criticizing Ms. Houston's job performance including one lie—that a surgeon had asked her leave the room during a procedure at McLeod—that was so outrageous and provably false that Mr. Garner changed it five times before withdrawing it entirely on November 14, 2018. Am. Compl. ¶ 100. On October 22, 2018, Medtronic's human resources department began proceedings that resulted in a decision to terminate Ms. Houston for "incompetence." Am. Compl. ¶ 101.

Ms. Houston did not transform from Medtronic's top-performing sales representative to an incompetent who does not work hard enough, who does not show up to work on time, and who is kicked out of the room by clients, in a few weeks that just happened to be immediately after she refused to deny that Medtronic staplers might have the manufacturing issue reported by numerous surgeons she was working with. Am. Compl. ¶ 102. These actions were retaliation for Ms. Houston's whistleblowing—specifically, her refusal, in meetings with Mr. Bland and Dr. Rose, to deny that there was an issue with the staplers and to agree that the adverse events were due to surgeons' "user error." *Id.*

On December 10, 2018, Ms. Houston was informed that she would be terminated for "incompetence," only seven months after she was the number one sales representative in the entire country and only three months after she reported concerns about the safety of Medtronic surgical

staplers at McLeod. Am. Compl. ¶ 104. As a result, she found herself in the unenviable position of an unemployed woman in her 50s with highly specialized skills, a non-compete agreement, a compromised personnel file, and a black mark on the brightest spot on her resume. Am. Compl. ¶ 105. Ms. Houston told her children on Christmas Day that she would soon be losing her job and her only source of income. In January 2019, as her termination was being processed, she was still the highest-performing sales representative in Mr. Garner's region, despite having been effectively suspended since October 2018. Am. Compl. ¶ 106.

5. After Medtronic terminates Ms. Houston, the defective staplers continue to injure patients, and McLeod is forced to buy its way out of its contract with Medtronic so that it can return to using Johnson & Johnson products that do not injure patients.

After Medtronic terminated Ms. Houston, its defective surgical staplers continued to injure patients at McLeod. Am. Compl. ¶ 107. McLeod was forced to pay for an early termination of its "conversion" agreement with Medtronic and to return (at a premium) to its former relationship with Johnson & Johnson, which sells surgical staplers manufactured in accordance with cGMP that are rarely recalled and do not injure patients. Am. Compl. ¶ 108. The "conversion" agreement was officially terminated on October 4, 2019. *Id.*

B. Procedural History

Ms. Houston filed the instant action on September 23, 2020. It remained under seal for over three years before the Government declined to intervene on November 22, 2023, and the case was unsealed on November 27, 2023. Ms. Houston then retained new counsel and filed an amended complaint on August 23, 2024. Medtronic moved to dismiss the amended complaint on October 15, 2024.

II. Legal Standard

To survive a Rule 12(b)(6) motion to dismiss for failure to state a claim, a complaint must "state a claim to relief that is plausible on its face" when all non-conclusory allegations are

assumed true and all reasonable inferences are drawn in favor of the complainant. *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 681 (2009). When alleging fraud, a plaintiff must also satisfy the heightened pleading standard of Rule 9(b), which provides that when alleging fraud "a party must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). But "intent, knowledge, and other conditions of a person's mind may be alleged generally." *Id.* "To satisfy Rule 9(b), a plaintiff asserting a claim under the [FCA] 'must, at a minimum, describe the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby.'" *United States ex rel. Nathan v. Takeda Pharms. N. Am., Inc.*, 707 F.3d 451, 455–56 (4th Cir. 2013) (quoting *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 379 (4th Cir. 2008)). All non-scienter elements of a substantive FCA claim must be pleaded with particularity under Rule 9(b). *United States ex rel. Taylor v. Boyko*, 39 F.4th 177, 190 (4th Cir. 2022). But an FCA retaliation claim does not require a showing of fraud. *See United States ex rel. Grant v. United Airlines Inc.*, 912 F.3d 190, 200 (4th Cir. 2018) ("Unlike [ ] substantive FCA claims, retaliation claims under § 3730(h) are not subject to Rule 9(b)'s heightened particularity requirement. Instead, a plaintiff need only satisfy Rule 8(a)'s notice-pleading standard.").

III. Argument

The FCA imposes liability on anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). "In general, a False Claims Act relator is required to allege four elements: (1) there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money or to forfeit moneys due (i.e., that involved a 'claim')." *Boyko*, 39 F.4th at 188 (footnote and internal quotation marks omitted).

Medtronic's main argument for dismissal is that Ms. Houston purportedly failed adequately to allege the first element, a false statement or fraudulent conduct. Medtronic principally argues that Ms. Houston asserts a "fraud of the FDA" claim disallowed by Fourth Circuit precedent. As explained below, that is a strawman argument. Ms. Houston asserts a worthless services claim. Medtronic caused McLeod to present claims to the Government for payment for worthless surgical services by knowingly selling defective surgical staplers to McLeod. The defective staplers made the surgical services worthless because they caused acute injury to government-beneficiary patients requiring further medical care at Government expense. Medtronic alternatively argues a worthless services theory has not been adequately pleaded, or at least not pleaded with particularity as to falsity or materiality, but as explained below, that argument also fails. Medtronic tries to analogize to inapposite cases in which services were alleged to be worthless based on conclusory assumptions about the importance of a possible regulatory violation (i.e., "fraud on the FDA" claims), but in this case Ms. Houston pleads specific products failed due to a specific defect and caused injury in specific procedures at specific times and places, and as a result those procedures failed to satisfy the statutory "reasonable and necessary" requirement for Medicare or Medicaid reimbursement. Ms. Houston has also pleaded with particularity the fraudulent course of conduct to conceal the defect that she personally witnessed.[1]

Medtronic also argues this action is barred by the public disclosure bar, and that Ms. Houston fails to allege a retaliation claim, but those arguments appear to be mere makeweight. Medtronic does not identify any public disclosure of the stapler defect at issue, nor of the

[1] Medtronic has not challenged the allegations regarding the scienter and presentment elements of Ms. Houston's substantive FCA claim.

fraudulent scheme to conceal it. And as explained below, Medtronic's argument that Ms. Houston fails to meet the lenient pleading standard for a retaliation claim is tendentious beyond absurdity.

A. Relator alleges fraudulent conduct by Medtronic.

1. Relator does not allege a "fraud on the FDA" claim.

Ms. Houston does not allege a "fraud on the FDA" claim, despite Medtronic's use of intensive adverbs to assert the contrary. *See* Mem. Supp. Mot. Dismiss 6 ("This is *clearly* Relator's attempt to advance a 'fraud on the FDA' theory . . . . Her argument is *clearly* a *poorly* disguised 'fraud on the FDA' theory . . . ." (emphasis added)). Ms. Houston alleges that by knowingly selling defective surgical staplers to McLeod under an exclusive contract, Medtronic knowingly caused McLeod to present claims to the Government for payment for worthless services—the surgical procedures using those defective staplers that injured beneficiaries of Government health care programs. Am. Compl. ¶¶ 109–19. Those injuries necessitated further medical care at Government expense for the injured patients. Am. Compl. ¶ 115.

Ms. Houston's allegations regarding Medtronic's deception of the FDA through inaccurate adverse event reports help plead Medtronic's scienter as well the materiality and fraudulent course of conduct elements which must be pleaded with particularity. Medtronic did knowingly deceive the FDA, but that is not the fraud for which Ms. Houston seeks recovery in the instant action. Medtronic is correct that the use of a stapler, which but for Medtronic's noncompliance with FDA regulations would have been subject to a recall, would not be, in itself, material to Medicare or Medicaid's decision to pay for an appendectomy or other surgical procedure using that stapler. This is why Medtronic's brief leads with a rebuttal of a strawman argument—it is easier for Medtronic to place an argument of its own choosing in Ms. Houston's mouth and then decisively rebut that argument than somehow explain how the worthlessness of a service could be immaterial to the Government's decision to pay for that service.

But Ms. Houston, not Medtronic, is "master of her complaint and determines which claims to bring." *Johnson v. Charlotte-Mecklenburg Sch. Bd. of Educ.*, 20 F.4th 835, 844 (4th Cir. 2021) (brackets and internal quotation marks omitted). In Ms. Houston's complaint, the fraud at issue is not Medtronic's violation of FDA regulations. The fraud at issue is knowingly causing worthless surgical services to be billed to the Government, by knowingly placing defective surgical tools in the hands of surgeons operating on beneficiaries of Government healthcare programs. Am. Compl. ¶¶ 109–19. Ms. Houston is required to plead "with particularity the circumstances constituting" that fraud. Fed. R. Civ. P. 9(b). Part of the particular circumstances constituting that fraud is the specific defect in the specific stapler products identified in the complaint. Am. Compl. ¶ 90. Another part is the specific injuries suffered by patients, like the patient whose bowels are seen spraying blood into the abdominal cavity from an injury caused by Medtronic's staplers. Am. Compl. ¶¶ 67, 73. Another part is the numerous and angry complaints from surgeons to Medtronic. Am. Compl. Ex. 53. Another part is Medtronic's evasive response to those complaints. Am. Compl. ¶¶ 72, 74–75, Ex. 55. Another part is how Medtronic deceived the FDA regarding those complaints to conceal the defect. Am. Compl. ¶ 90. Another part is Medtronic's extensive history of stapler defects and recalls, which made it especially averse to yet another recall. Am. Compl. ¶ 82–88. Another part is Medtronic's immediate retaliation against its top sales representative when she would not agree to conceal the truth. Am. Compl. ¶ 95–106. And so on. The fraud in this case is not a mere regulatory violation.

Medtronic repeatedly cites *United States ex rel. Rostholder v. Omnicare, Inc.*, for the proposition that the Fourth Circuit "declined to even entertain" the worthless services theory in the context of purportedly defective medical products, because in a footnote the Fourth Circuit stated "[b]ecause adulterated drugs are subject to reimbursement by Medicare and Medicaid and

therefore any claim for payment cannot be 'false,' we do not separately address relator's arguments for FCA liability under 'implied certification' or 'worthless services' theories." 745 F.3d 694, 702 n.7 (4th Cir. 2014). But the case is inapposite. The FDA prohibits packaging non-penicillin drugs in the same facility as penicillin, to prevent the possibility of allergic reactions from penicillin cross-contamination. 21 C.F.R. § 211.42(d) & § 211.46(d)). The *Rostholder* relator alleged the defendant violated that rule because its adjacent penicillin and non-penicillin drug packaging facilities had a common air handling system, so that its non-penicillin drugs were adulterated and claims to government programs for payment for those drugs were false. 745 F.3d at 697. The district court dismissed the complaint because, *inter alia*, the relator failed to plead false or fraudulent conduct by the defendant. *Id.* at 698. As a fallback argument, the *Rostholder* relator argued on appeal that conduct rendered the drugs "worthless" even though he admitted in the district court that theory was inapplicable. Appellee's Brief 45, No. 12-2431 (Apr. 12, 2013). But the *Rostholder* relator did not allege that any drug failed to operate as expected nor did he allege that any drug actually was contaminated with penicillin. *Id.* at 46. The Fourth Circuit therefore would not consider a worthless services argument because the relator did not allege any drug was actually contaminated or did not perform as expected. Here, however, Ms. Houston alleges that staplers failed on specific occasions, that patients were actually harmed on specific occasions, that specific Medtronic executives were told at specific meetings, and that those executives took specific wrongful actions to conceal the issue, which resulted in further harm to specific patients. Am. Compl. ¶¶ 59–94.

2. Relator has adequately alleged a worthless services claim.

Medtronic argues that "Even if Relator can provide these adverse clinical events occurred [patients injured by defective Medtronic staplers], those facts would not establish an FCA violation because her allegations include no cognizable basis for a conclusion that any services involving

the Medtronic staplers were worthless." Mem. Supp. Mot. Dismiss 10. The "cognizable basis" that the first procedure was worthless is the need to have a second procedure to correct the injury caused by the first procedure. Am. Compl. ¶ 67. As Medtronic concedes, the general standard for government coverage of a surgical procedure is that it be "reasonable and necessary." Mem. Supp. Mot. Dismiss 10 (quoting 42 U.S.C. § 1395y). The point of bowel surgery is to *solve* problems with the bowels, not to *create* problems requiring further surgery. Contrary to Medtronic's argument, Ms. Houston has alleged that the surgeries at issue were not reasonable and necessary. There is nothing "reasonable and necessary" about creating injury or creating a need for blood transfusions and further surgery. Am. Compl. ¶¶ 67, 73. As stated in the Amended Complaint:

> The services were worthless because, in the face of full disclosure of all relevant facts, neither the Government nor anyone else would buy the service at any price. No one would purchase a colon resection, for example, from a provider who disclosed that he would use defective tissue staplers causing major bleeding issues and requiring follow up surgery to correct. Everyone would instead purchase the needed service from someone using non-defective surgical tools. The market value of the defective service is zero because no fully informed buyer would agree to pay for it. To get anyone to agree to pay for it requires fraud.

Am. Compl. ¶ 116; *cf. United States v. Marcus*, 82 F.3d 606, 610 (4th Cir. 1996) (holding, in a criminal fraud action, that an adulterated drug is worthless if consumers would not purchase it at any price if they were informed about the adulteration).

Ms. Houston anticipated that Medtronic might argue the surgeries at issue were not worthless as a matter of law because they provided some benefit—colons were resected and appendices were removed, arguably beneficial outcomes even if doing so resulted in injuries requiring another operation to correct. To rebut that anticipated argument, Ms. Houston cited numerous cases from the context of nursing homes. Non-compliant nursing homes facing worthless services claims often argue they did provide some valuable services to resident patients (food, shelter, etc.) and so their services cannot be entirely worthless. Courts generally reject that

argument. *See, e.g.*, *United States v. Am. Health Found. Inc.*, No. CV 22-02344, 2023 WL 2743563, at *13 (E.D. Pa. Mar. 31, 2023) ("A bundle of services can, on average, be worthless even if some of them were administered properly."); *United States v. Villaspring Health Care Ctr., Inc.*, No. CIV.A. 3:11-43-DCR, 2011 WL 6337455, at *5 (E.D. Ky. Dec. 19, 2011) (("It is not necessary to show that the services were completely lacking; rather, it is also sufficient to show that 'patients were not provided the quality of care' which meets the statutory standard."); *see also, e.g.*, *United States ex rel. Scharber v. Golden Gate Nat'l Senior Care LLC*, 135 F. Supp. 3d 944 (D. Minn. 2015); *United States ex rel. Academy Health Ctr., Inc. v. Hyperion Found., Inc.*, No. 10-552, 2014 WL 3385189 (S.D. Miss. July 9, 2014); *United States v. NHC Healthcare Corp.*, 115 F. Supp. 2d 1149 (W.D. Mo. 2000). The point of a nursing home is to provide nursing home care, not merely to provide room and board. By analogy, an appendectomy may be rendered worthless even if the appendix is successfully removed if the operation leaves the patient with an acute injury (like uncontrolled bleeding) requiring abdominal surgery to prevent possible death. The point of the appendectomy was to correct an acute condition requiring abdominal surgery to prevent possible death. Merely substituting another such acute condition is not a "reasonable and necessary" procedure meeting the Medicare and Medicaid standard for coverage. *See* CMS, *Medicare Program Integrity Manual* § 13.5.1 (defining a service as "reasonable and necessary" if the procedure is "safe and effective" and "furnished in accordance with accepted standards of medical practice" (capitalization modified)); *see also id.* § 13.3 (incorporating § 13.5.1's definition of reasonable and necessary for individual claim determinations).

Medtronic, however, does not appear to argue that the surgical procedures at issue here were not worthless because they may have achieved some positive outcomes despite the injuries they caused. Instead, Medtronic appears to argue that surgical procedures do not involve

"coverage and payment standards analogous to the nursing home care requirements" in those nursing home cases. Mem. Supp. Mot. Dismiss 11. Again, this is a strawman argument. Ms. Houston does not make a nonsensical argument that Medtronic's surgical staplers failed to meet residential nursing home standards of care. Ms. Houston argues they caused surgical procedures to fail to meet the "reasonable and necessary" standard for Medicare and Medicaid coverage of surgical procedures.

3. Relator has alleged a worthless services claim with particularity.

a. Relator has alleged a fraudulent course of conduct with particularity.

Medtronic argues Ms. Houston fails to allege a false statement. The legal standard on falsity is disjunctive: "a relator must plausibly allege four distinct elements: "(1) [ ] there was a false statement *or* fraudulent course of conduct. . . ." *Rostholder*, 745 F.3d at 700 (emphasis added). Ms. Houston has alleged both a false statement and a fraudulent course of conduct with particularity. "[A] doctor's certification to the government that a procedure is 'reasonable and necessary' is 'false' under the FCA if the procedure was not reasonable and necessary under the government's definition of the phrase." *United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 743 (10th Cir. 2018). The procedures performed at McLeod using the GIA80 stapler in and after August 2018 were not "reasonable and necessary" under the Government's definition of the phrase because they were not "safe and effective" nor "furnished in accordance with accepted standards of medical practice." *See* CMS, *Medicare Program Integrity Manual* § 13.5.1. The particular factual allegations supporting this are the surgeon complaints and reports regarding the failure of the GIA80 in specific surgical procedures on specific dates. *E.g.*, Am. Compl. Ex. 53. Despite not being "reasonable and necessary," some of these procedures were billed to Government health programs. Am. Compl. ¶ 78. Those are false statements pleaded with particularity.

McLeod, of course, did not commit fraud because it did not act with scienter. But Medtronic did when causing McLeod to present those false payment claims. Medtronic knew the truth and intentionally acted to conceal the truth. Medtronic did so to make profits even though it knew it was thereby causing false claims to be presented to the Government. Ms. Houston alleges this fraudulent course of conduct with particularity as to time, place, and content. Ms. Houston has alleged, *inter alia*, specific procedures on specific dates, Am. Compl. ¶ 67, specific complaints and reports of patient injuries from named physicians regarding specific malfunctions in a specific Medtronic product causing patient injury in those specific procedures, Am. Compl. ¶¶ 67, 73, Ex. 53, specific communications about the defects, Am. Compl. ¶ 69, meetings on specific days, identifying Medtronic managers and other persons present and what they said, Am. Compl. ¶¶ 72, 75–76, specific statements by Medtronic to the FDA misrepresenting physician complaints, Am. Compl. ¶ 90, and specific acts of retaliation against Ms. Houston, Am. Compl. ¶ 93, 99–101.

b. Relator has alleged materiality with particularity.

The particular facts establishing materiality are the same as the facts establishing the worthlessness of the surgical operations using Medtronic's defective staplers and the falsity of the claim for payment for those worthless services. These facts are alleged with specificity as to time, place, and content. *E.g.*, Am. Compl. ¶ 67, 69, 72–73, 75–76, Ex. 53. No one can argue the worthlessness of the services could be immaterial to the Government's decision to pay claims for those worthless services. The statutory standard for payment is "reasonable and necessary," 42 U.S.C. § 1395y, and worthless services cannot be "reasonable and necessary," CMS, *Medicare Program Integrity Manual* § 13.5.1 (providing that "reasonable and necessary" procedures meet "the patient's medical need").[2]

[2] Medtronic complains that Ms. Houston "does not identify any coverage or payment requirement material to any decisionmaker for any of the relevant government healthcare programs." Mem.

Medtronic avoids this by again attacking a strawman "fraud on the FDA" theory, this time with a discussion of a purportedly "similar allegation" in *United States ex rel. Roop v. Hypoguard USA, Inc.*, 559 F.3d 818 (8th Cir. 2009). In *Roop*, the relator alleged that the defendant "caused the submissions of false claims by selling products the FDA would not have approved but for [the defendant's] fraudulent submission in the pre-market approval process." *United States ex rel. Roop v. Hypoguard USA, Inc.*, No. CIV. 07-1600 ADM/AJB, 2007 WL 2791115, at *2 (D. Minn. Sept. 24, 2007). That is a "fraud on the FDA" theory that the district court rejected because it was unsupported by particular facts alleging what the FDA was told in the pre-market approval process, *id.*, and the circuit affirmed for various reasons including an observation that the relator did not allege how the defendant's alleged failure to submit MDR reports to the FDA would have been material to "the government's decisions to pay countless unidentified Medicare reimbursement claims submitted by [the defendant's] distributors," *Roop*, 559 F.3d at 825. In *Roop*, a worthless services claim "was not alleged" because the glucose meters admittedly did work when used properly. 559 F.3d at 824. The *Roop* relator also alleged the defendant's glucose blood testing meters were defective because they require a specific amount of blood to operate correctly and do not contain a device to warn a user when the blood sample is too small to produce an accurate reading. *Roop*, 2007 WL 2791115, at *2. That claim was dismissed because, *inter alia*, the Roop relator was "unable to identify any authority that blood glucose meters requiring a specific blood sample size and that do not contain a short-fill detection device are defective." *Id.*

Supp. Mot. Dismiss 15. But Medtronic admits the requirement material to any decisionmaker is set forth in 42 U.S.C. § 1395y. A plaintiff "need not plead law." *See, e.g.*, *Doe v. Smith*, 429 F.3d 706, 708 (7th Cir. 2005). Rule 9(b) requires a plaintiff to plead *facts* setting forth the "circumstances constituting fraud" with particularity, which Ms. Houston has done.

Roop is inapposite because here the claim is worthless services, not "fraud on the FDA," and the authorities stating that the GIA80 staplers were defective are the surgeons who submitted reports stating exactly that, attached to the Amended Complaint. Am. Compl. Ex. 53.

B. The public disclosure bar does not bar Relator's claims.

1. Medtronic has not identified any prior disclosure of the stapler defect reported by Relator—much less any prior disclosure of fraudulent conduct related to that defect.

The alleged defect in this case is that one or more lots of GIA80 staplers used at McLeod in and after August 2018 had a manufacturing defect causing them to cut past the staple line. Am. Compl. ¶¶ 61–63, 67. This is alleged to be a manufacturing defect, not a design defect, as earlier lots of the GIA80 staplers did not exhibit this defect. Am. Compl. ¶¶ 52, 74, 75. Medtronic has not identified any public disclosure of this defect, must less any disclosure of a fraudulent scheme regarding it. Instead, Medtronic attempts to distract the Court with a discussion of facts outside the pleadings about different defects with different staplers. A survey of adverse incidents involving at least seven types of staplers from 1991 to 2001, published 18 years before the GIA80 issues at McLeod, has no relevance to this litigation. *See* Mem. Supp. Mot. Dismiss 17–18 & Ex. A. A news report regarding injury reports related to "about 100 medical devices" submitted in the FDA's Alternative Summary Reporting (ASR) program has no relevance to this litigation. *See* Mem. Supp. Mot. Dismiss 18 & Ex. B. Ms. Houston has pleaded that Medtronic ceased reporting stapler-related incidents through the ASR program in July 2017, well before the beginning of the defect at issue in this case. Am. Compl. ¶ 84. The litigation reported in Exhibit C to the memorandum supporting the motion to dismiss involved different defects with different staplers, defects that led to misfiring without engaging the staples (ECF No. 69-5 at 4) or "creating holes without leaving behind staples or not properly closing implanted staples" (ECF No. 69-5 at 3), not the incision beyond the staple line alleged here regarding the GIA80. The 2018 stapler recalls

described in the Amended Complaint at Paragraphs 87 and 88 and attached to the memorandum supporting the motion to dismiss as Exhibits D and E (and discussed in Exhibit F) concerned a different issue the Endo GIA 45mm Curved Tip Articulating Vascular/Medium Reload with Tri-Staple and the Endo GIA 45mm Extra Thick Black Articulating Reload with Tri-Staple Technology, not the 80mm GIA80 at issue in this case.

2. Relator's claims cannot be based on prior public disclosures because there were no such public disclosures.

Medtronic proposes the following framework for "analyzing the public disclosure bar": "'(1) is there a qualifying public disclosure? (2) if yes, is the disclosed information the basis of the relator's suit? (3) and, if so, is the relator the original source of that information?" Mem. Supp. Mot. Dismiss 17 (quoting *United States ex rel. Maharaj v. Est. of Zimmerman*, 427 F. Supp. 3d 625, 646 (D. Md. 2019)). Ms. Houston agrees that is the proper analytic framework. Since Medtronic cannot identify any public disclosure of the defect at issue—the GIA80 cutting beyond the staple line—or any public disclosure of a fraud related to that defect, the answer to the first question must be "no" and the Court should not consider whether the disclosed information is the basis of the suit or whether the relator is an original source of the information.

Since there was no public disclosure, Medtronic's attempts to argue that Ms. Houston's allegations were based on the non-existent disclosure comically miss the mark. Medtronic can offer only foggy phrasing like "the symmetry is striking between Relator's allegations . . . and the substance of the many public reports . . . about the performance of Medtronic's . . . surgical staplers." Mem. Supp. Mot. Dismiss 19–20. Of course, it is not surprising that a report of a specific defect with a specific surgical stapler would have some "symmetry"—whatever that means—with other reports of different defects with different surgical staplers. Nor is it surprising that reports of patient injuries caused by that specific defect would be "consistent in kind"—

whatever that means—with the "pre-existing public record" of injuries caused by other defects in other types of staplers. *Id.* at 21. And Ms. Houston has no idea why Medtronic then pivots to a discussion of allegations regarding the ASR reporting program. Medtronic stopped reporting stapler incidents to the ASR program about one year before the defect at issue in this case began. Am. Compl. ¶ 84. The point of discussing the ASR program in the Amended Complaint is scienter and *res gestae*—Medtronic had a long history, hidden for years, of various defects with its various staplers, and in August 2018 Medtronic was under extra pressure to hide stapler defects because it could no longer hide them in a non-public summary database.

3. Relator is an original source of information.

Medtronic's attempt to argue Ms. Houston is not the original source of information never disclosed by anyone except Ms. Houston is without merit. Ms. Houston provides meeting dates and attendees, internal emails, handwritten internal complaint forms from surgeons who used the defective staplers and witnessed the defect, and even a video recording of a patient being injured by a defective stapler during a surgery. *E.g.*, Am. Compl. ¶ 67, 69, 72–73, 75–76, Ex. 53. This is not "repackaged information disclosed in news media articles." *Cf.* Mem. Supp. Mot. Dismiss 22. In discovery, Medtronic will disavow this meritless argument. Medtronic representatives might testify that the GIA80 was not defective, or that if it was defective they did not know, but they certainly will not testify that the GIA80 *was* defective, but that the defect was "well-known to the public for years through media and FDA agency reports"—which would admit that Medtronic knowingly sold defective medical devices. *See id.*

C. Relator has alleged a cognizable retaliation claim.

To plead an FCA retaliation claim, "a plaintiff must allege facts sufficient to support a 'reasonable inference' of three elements: (1) he engaged in protected activity; (2) his employer knew about the protected activity; and (3) his employer took adverse action against him as a

result." *Grant*, 912 F.3d at 200. These elements need not be pleaded with particularity, rather "a plaintiff need only satisfy Rule 8(a)'s notice-pleading standard." *Id.* As explained below, Medtronic's arguments that Ms. Houston has failed to meet this lenient pleading standard fall flat.

1. Relator's conduct was a protected activity.

There are two types of protective activity: acts in furtherance of an FCA action and efforts to stop violations of the FCA. *Grant*, 912 F.3 at 200. To constitute protected activity to stop a violation of the FCA, "an act must be motivated by an objectively reasonable belief that the employer is violating or will soon violate the FCA, that the employee took action to stop the FCA violations, and that the employee has a nexus to the FCA violation." *United States ex rel. Oldham v. Centra Health, Inc.*, 548 F. Supp. 3d 568, 575 (W.D. Va. 2021) (citing *Grant*, 912 F.3 at 201–02).

Ms. Houston alleges an objectively reasonable belief that Medtronic was committing fraud by concealing the dangerous stapler defects at McLeod. She received numerous complaints of defects causing injury to patients, which she communicated to her supervisor. When he did not act, she communicated with numerous other managers at Medtronic, including her manager's manager, six other Medtronic sales representatives, the medical director at the Medtronic manufacturing facility in North Haven, Connecticut, Medtronic's global quality complaint manager, and Medtronic's stapling product manager. Am. Compl. ¶ 69. She attempted to remove staplers for testing. Am. Compl. ¶ 70. She participated in meetings with McLeod management and Medtronic management on September 19, September 27, and October 1, 2018, at which she refused to tell McLeod management that the patient injuries were due to McLeod surgeon error rather than a Medtronic product defect. Am. Compl. ¶¶ 72, 74–75. Her insistence on telling the hospital the truth about the surgical tools engaged her superiors. Am. Compl. ¶ 76. She steadfastly held to the truth regardless, because she wanted to stop Medtronic's fraudulent course of conduct

that was harming patients, including patients whose care was funded by Government health programs. Am. Compl. ¶¶ 78, 102. Medtronic's argument that a single parent in her early 50s sacrificing her livelihood and the only career she ever had to expose fraud "is not the heroine she claims to be" because her action "merely constitutes reporting of complaints and suggestions for improvement" "which . . . were part of her regular job duties" reads more like sarcasm than a good faith legal argument. *See* Mem. Supp. Mot. Dismiss 24, 26.

2. Relator's allegations regarding Medtronic's knowledge are fulsome.

Medtronic next argues that Ms. Houston fails to allege it knew about her protective activity. That is absurd. She communicated with numerous Medtronic executives. Am. Compl. ¶ 69. Medtronic managers were in the room with the client when she told the truth. Am. Compl. ¶¶ 72, 74–75. She alleges they were enraged by their knowledge of her protected activity. Am. Compl. ¶ 76. It is tendentious for Medtronic to argue that a Medtronic executive two levels above Ms. Houston publicly yelled at her that he didn't ever want to hear her discuss the possibility of a defect with the GIA80 stapler again because she was putting the conversion at risk in response to her "performing the ordinary duties of her job by submitting adverse event reports to Medtronic's quality reporting system." *See* Mem. Supp. Mot. Dismiss 26. He did that because he was angry that she told an uncomfortable truth in the meetings they had just held with the client about the GIA80 stapler.

3. Medtronic cannot plausibly argue Medtronic did not retaliate against her.

Medtronic argues that the allegation that it retaliated against Ms. Houston is not "plausible" without any discussion of what actions it took against Ms. Houston or when. *Id.* That is because the timeline of the retaliation is impossible to rebut:

- In late April 2018, Ms. Houston was Medtronic's top sales representative in the country.
- In July 2018, she was promoted (again).
- In late August 2018, she began reporting concerns about defective GIA80 staplers that were harming patients.
- In early December 2018, she was informed she would be terminated for incompetence.

Cf. Grant, 912 F.3d at 203 (citations and internal quotation marks omitted):

> With respect to the third element, the timeline of events alleged in the [amended complaint] supports a reasonable inference that [the defendant] terminated [the relator] because he engaged in protected activity.
>
> . . .
>
> An employer undertakes a materially adverse action opening it to retaliation liability if it does something that well might have dissuaded a reasonable worker from making or supporting a charge of discrimination. Here, [the relator's] termination, following close on the heels of his numerous complaints, represents the ultimate action that an employer can take against a reasonable worker for whistleblowing.
>
> Accordingly, we hold that [the relator] has successfully pleaded retaliation under § 3730(h). The district court thus erred in holding that [the relator] failed to plead sufficient facts to withstand a motion to dismiss.

IV. Conclusion

For the foregoing reasons, the motion to dismiss should be denied.

[signature block follows]

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